

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

* * * * *

JENNIFER HIBBARD,	*	No. 07-446V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	
v.	*	Filed: April 12, 2011
	*	Released: May 25, 2011
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	entitlement, flu vaccine,
	*	dysautonomia, autonomic neuropathy,
Respondent.	*	postural tachycardia syndrome
	*	(POTS)

* * * * *

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA., for petitioner;
Glenn A. MacLeod, United States Dep't of Justice, Washington, D.C., for respondent.

DECISION DENYING COMPENSATION¹

Jennifer Hibbard received a flu vaccine in 2003, and she claims that the flu vaccine caused a neurological problem known as dysautonomia. Pet'r Br., filed June 21, 2010, at 1. She seeks compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 et seq. (2006).

Ms. Hibbard presents a theory that the flu vaccine can cause the body to attack itself, resulting in an injury. Ms. Hibbard contends that in her case, the part of the body that was attacked was the sympathetic component of her autonomic nervous system. As explained in more detail below, such damage is labeled "autonomic

¹ When this decision was originally issued, the parties were notified that the decision would be posted in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). The parties were also notified that they may seek redaction pursuant to 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b). Petitioner made a timely request for redaction; however, petitioner's motion was denied and this decision is now released as issued originally.

neuropathy.” Ms. Hibbard further argues that her autonomic neuropathy manifested as a type of dysautonomia, known as postural orthostatic tachycardia syndrome (“POTS”). Pet’r Br. at 35-36.

Although it is accepted that Ms. Hibbard has POTS, POTS has more than one cause. Ms. Hibbard advances the theory that her POTS is due to damage in her autonomic nerves caused, ultimately, by the flu vaccine. Evaluating the evidence for and against the theory offered by Ms. Hibbard is not necessary because Ms. Hibbard’s claim fails for a different reason. Ms. Hibbard has failed to present preponderant evidence that she suffers from autonomic neuropathy. Consequently, she is not entitled to compensation.

I. Procedural History

After Ms. Hibbard filed her petition, she filed medical records and obtained a report from Dr. Thomas Morgan. Dr. Morgan has been board-certified in neurology since 1977. Tr. 14; see also exhibit 37 (curriculum vitae).² Dr. Morgan opined that “Ms. Hibbard sustained a post influenza vaccine immunization autonomic neuropathy with signs and symptoms well documented in the record of dysautonomia.” Exhibit 36 at 5.

Respondent obtained a report from Dr. Vinay Chaudhry. Dr. Chaudhry teaches neurology at the Johns Hopkins University School of Medicine. He has board certification in four disciplines -- neurology, neuromuscular diseases, clinical neurophysiology, and electrodiagnostic medicine. Tr. 200-03; see also exhibit C (curriculum vitae).³ Dr. Chaudhry, initially, opined that “there is no causal link between the flu vaccine and [Ms. Hibbard’s] multiple symptoms.” Exhibit A (report dated June 1, 2008). After reviewing Dr. Morgan’s report, Dr. Chaudhry opined that

² In addition to his practice in neurology, Dr. Morgan works as an independent medical examiner, who attempts to determine the “nature, cause and extent of a person’s injury or disease.” Tr. 16. In his more than thirty years as a neurologist, Dr. Morgan has not treated a patient with dysautonomia caused by autonomic neuropathy. Tr. 144. He also has not treated any patients with POTS. Tr. 172.

³ Dr. Chaudhry only sees patients who have a disorder in the peripheral nervous system, including people with autonomic neuropathy. In conjunction with cardiologists, Dr. Chaudhry sees one or two people with POTS per year. Tr. 202-03.

“There is no objective sign or laboratory test that has demonstrated that Ms. Hibbard has peripheral neuropathy.” Exhibit D.

Following these reports, a hearing was held on August 12, 2009. The testimony was not completed during this session and an additional hearing was held on February 23, 2010. During the interim, Dr. Morgan and Dr. Chaudhry prepared supplemental reports, explaining the bases for their opinions regarding Ms. Hibbard’s autonomic nervous system. Exhibit 52 and exhibit H.

The February 23, 2010 hearing concluded the evidentiary development of Ms. Hibbard’s case. Afterwards, the parties filed briefs. With the filing of Ms. Hibbard’s reply brief, the case is ready for adjudication.⁴

II. Background

The autonomic nervous system helps maintain balance (homeostasis) inside the body. It has two components, the sympathetic component (the portion relevant to Ms. Hibbard’s case) and the parasympathetic component. Nerves in the sympathetic component control the heart, stomach, gut, and sweat glands. Tr. 36-37; see also tr. 340.

The sympathetic component is divided, depending upon whether the nerve is proximal or distal to a ganglion. A ganglion, in this context, is a group of nerve cells located outside the central nervous system that connects nerve endings. Tr. 349; Dorland’s Illustrated Medical Dictionary (31st ed. 2007) at 768. Nerves of the autonomic nervous system that are pre-ganglion are myelinated. Post-ganglion nerves are not myelinated. Tr. 349; tr. 44-48. Myelin is a substance that wraps nerves like insulation around a wire. See Dorland’s at 1237. For sympathetic nerves, the pre-ganglionic section is relatively short and the post-ganglionic section is relatively long. Tr. 349; Dorland’s at 1885 (defining sympathetic nervous system). These divisions of the autonomic nervous system were depicted in petitioner’s trial exhibit 1, pages 3-6, and a similar presentation appears in Dorland’s at 1883.

⁴ After the case was ready for adjudication, Ms. Hibbard filed a motion for an interim award of attorneys’ fees and costs, which was opposed. Respondent’s arguments in opposition were rejected and Ms. Hibbard’s motion was granted. Decision, filed March 7, 2011. The dispute over attorneys’ fees did not affect the outcome of Ms. Hibbard’s case.

The sympathetic component of the autonomic nervous system can be tested. Ways include taking a person's blood pressure, measuring a person's sweat, using a test called the Valsalva maneuver to see whether the person's blood pressure and heart rate change as the person breathes, and measuring catecholamines, which are hormones produced by the sympathetic nervous system. Tr. 211-13; see also Dorland's at 1118 (defining Valsalva maneuver) and at 310 (defining catecholamines). A thorough listing of different tests is provided in John M. Ravits, Autonomic Nervous System Testing, Muscle & Nerve (Aug. 1997), which was filed as exhibit F, tab 10.⁵ See 246-48 (discussing this paper). These tests are useful in detecting a malfunction in the nerves. When there is a problem in a peripheral nerve, the medical term is "neuropathy" and when the damaged nerve is part of the autonomic nervous system, the term is "autonomic neuropathy." Dorland's at 1287.⁶

When the autonomic nervous system does not function properly, the person suffers from dysautonomia. Dorland's at 583. It is critical to understand that the term "dysautonomia" is an umbrella term encompassing "autonomic neuropathy." Although autonomic neuropathy is dysautonomia, dysautonomia does not always mean there is autonomic neuropathy. Tr. 318 (Dr. Chaudry stating that dysautonomia "does not equate with autonomic neuropathy.")

One example of when dysautonomia is caused by something other than a problem in the autonomic nerves is dehydration. Dehydration can cause the heart to pump faster to maintain blood pressure. Tr. 220. The person would experience dysautonomia (in the sense of a higher than normal heart rate) but this dysautonomia would not be classified as autonomic neuropathy because the nerves functioned properly. Tr. 263-65; tr. 275; see also tr. 566. Another example is when the problem is in the ganglion. Tr. 380; tr. 422.

Dr. Chaudhry consistently differentiated between dysautonomia and autonomic neuropathy. As discussed below, Dr. Chaudhry opined that Ms. Hibbard suffered

⁵ This paper is a minimonograph issued by the American Association of Electrodiagnostic Medicine and is an often-quoted paper for providing standard laboratory values. Tr. 248.

⁶ When the sympathetic component of the autonomic nervous system and the parasympathetic component of the autonomic nervous system are damaged, the person suffers from "pandysautonomia." "Pan" means "all." Tr. 43. Pandysautonomia is considered to be a variant of Guillain-Barré syndrome. Tr. 255; tr. 473-76; exhibit 36, tab C (Allan H. Ropper et al., Guillain-Barré Syndrome, 109).

from the former, but not from the latter. Tr. 318-19. Dr. Morgan agreed that there is a distinction between dysautonomia and autonomic neuropathy. Tr. 535.

The differences between dysautonomia and autonomic neuropathy are important when considering POTS. In simple terms POTS means that the heart pumps faster when the person stands. Tr. 37-39; tr. 218. “Orthostatic” refers to an erect standing position. Dorland’s at 1361. “Tachycardia” refers to excessive rapidity in the heart. Id. at 1890; tr. 168. Strict diagnostic criteria for POTS require an increase of more than 30 beats per minute when standing and a certain amount of norepinephrine. Tr. 219; tr. 276; exhibit F, tab 14 (Giris Jacob et al., The Neuropathic Postural Tachycardia Syndrome, 343 No. 14 New Eng. J. Med. 1008 (2000)) at 1012. Often a tilt table is used to test for POTS. Tr. 537.

POTS may be caused by damaged nerves. One article, which was issued by the Mayo Clinic, states that the results of tests on people with POTS “support our initially postulated concept that POTS is a limited autonomic neuropathy.” Exhibit 38, tab A (Mark J. Thieben et al., Postural Orthostatic Tachycardia Syndrome: The Mayo Clinic Experience, 82(3) Mayo Clin Proc. 308 (2007)) at 312. This is the opinion advanced by Dr. Morgan. Tr. 61 (discussing this article). Dr. Chaudhry agreed that damage to nerves in the sympathetic nervous system can cause POTS. Tr. 468-69.

Although autonomic neuropathy can cause POTS, POTS has causes other than an autonomic neuropathy. Tr. 217 (Dr. Chaudhry stating “not all POTs patients have to have peripheral neuropathy. Now, some peripheral neuropathy can be POTs.”); Tr. 274-75; tr. 403; tr. 566. Dr. Chaudhry’s opinion is supported by the same Mayo Clinic article relied upon by Dr. Morgan. This article states that “Approximately 50% of patients had evidence of peripheral sudomotor denervation.” Exhibit 38, tab A (Thieben) at 312. As Dr. Chaudhry points out, this leaves approximately 50% of patients without problems in the sympathetic nerves of their legs. Tr. 262; tr. 275-76. Dr. Morgan also agreed that not all cases of POTS have peripheral neuropathy. Tr. 39; tr. 532.

This background provides a context for understanding the medical problems experienced by Ms. Hibbard. It is important to be mindful that “dysautonomia” is a broad term that sometimes, but not always, means autonomic neuropathy. This nomenclature is especially important when considering the specific type of dysautonomia known as POTS because POTS has several causes, of which one is a problem in the sympathetic nerves.

Ms. Hibbard was born in 1962. Exhibit 18 at 1. Since 1995, she taught first grade at a school in Quincy, Massachusetts. Exhibit 33 (Ms. Hibbard's affidavit) ¶ 1.

In May 2003, Ms. Hibbard was standing when she felt a wave of heat and lightheadedness. She lost consciousness for approximately 10 seconds and was taken by ambulance to a local emergency room. Exhibit 25 at 1. In the emergency room, she reported that she had lightheadedness during menses. A neurological examination, CT scan of her head, and routine laboratory tests were all normal. Exhibit 18 at 2. She was discharged the same day. Exhibit 18 at 2. The doctors did not conduct any specific tests for dysautonomia. Tr. 116-17; tr. 498-99.

Dr. Chaudhry characterized this May episode as an instance of dysautonomia. An episode of fainting is, by definition, a neurological problem. Tr. 380; tr. 491-92. Dr. Morgan agreed that events precipitate fainting, tr. 98-99, and that Ms. Hibbard's fainting in May was a symptom of autonomic dysfunction. Tr. 557-58.

After Ms. Hibbard was discharged from the emergency room for her fainting, she saw her primary care physician, Amy Schoenbaum, two days later. Dr. Schoenbaum stated that the episode was "probably related to some mild dehydration." Exhibit 23 at 230. Dr. Morgan agreed that the cause of the fainting was dehydration. Tr. 90.⁷

In July 2003, Ms. Hibbard saw Dr. Schoenbaum for an annual physical. Ms. Hibbard reported that it took "about a month" for her "to feel like herself" following the May fainting. But, by July 25, 2003, she had recovered and Dr. Schoenbaum reported that Ms. Hibbard was healthy. Exhibit 23 at 227. Dr. Morgan indicated that Ms. Hibbard's good health in July 2003 suggests that the May 2003 fainting was a single episode. Tr. 109-10; see also tr. 189-90.⁸

⁷ Dr. Chaudhry stated that the May 2003 fainting may be related to the problems that Ms. Hibbard started to experience in November 2003. Tr. 498-99. One of Ms. Hibbard's treating doctors, Dr. Kim, who is an endocrinologist, stated that Ms. Hibbard's "symptoms seem to have begun in May of 2003 when she had an episode of syncope. At this time, this was not concerning and routine evaluation was unremarkable. However, in retrospect, Mrs. Hibbard notes this as the start of a syndrome." Exhibit 23 at 254 (report dated Jan. 16, 2004).

⁸ Ms. Hibbard's good health in July 2003, is not inconsistent with Dr. Chaudhry's theory that Ms. Hibbard's fainting in May 2003 was linked to her

On November 1, 2003, Ms. Hibbard received the influenza vaccine. Exhibit 31 at 1. Ms. Hibbard's petition claims that this vaccination caused her subsequent neurological problems. Amended Pet., filed Feb. 27, 2008, at 1.

On November 5, 2003, Ms. Hibbard "started feeling as though I were coming down with 'a bug.'" On November 8, 2003, Ms. Hibbard, although still not feeling well, brought some students shopping as she had promised as part of a fund-raising auction. While with the students, she felt nauseated, sweaty, flushed, chills and dizzy. She thought that she might vomit and felt like she might pass out. She was sensitive to lights. After she got home, she continued to feel ill for the next few days. Exhibit 33 (affidavit) ¶¶ 5-12.

On November 11, 2003, Ms. Hibbard saw an associate of Dr. Schoenbaum, Jeffery Wu. Ms. Hibbard provided a history of her recent illness that is consistent with the previous paragraph. Dr. Wu diagnosed Ms. Hibbard as having an "evolving sinusitis" probably due to a "viral respiratory infection." Dr. Wu prescribed amoxicillin. Exhibit 23 at 224-25.

On November 15, 2003, Ms. Hibbard saw another doctor in the same practice as Dr. Schoenbaum, Helen Leibner. Dr. Leibner recorded that Ms. Hibbard has felt "progressively worse," and "extremely tired and weak." Ms. Hibbard also has more "dizziness." Dr. Leibner discontinued the amoxicillin and stated that Ms. Hibbard's symptoms are most consistent with a "viral syndrome." Exhibit 23 at 222-23.

For the next months, Ms. Hibbard continued to feel ill. Exhibit 33 at 5. On December 12, 2003, Ms. Hibbard went to Dr. Schoenbaum for problems of lightheadedness, increased bowel movements with loose stools, shortness of breath, and the constant feeling like she would pass out. Dr. Schoenbaum referenced Ms. Hibbard's November 1, 2003 flu vaccination. She referred Ms. Hibbard to the emergency room at Brigham and Women's Hospital. Exhibit 23 at 153; exhibit 33 (affidavit) ¶ 15.

At Brigham and Woman's Hospital, she was seen by a neurologist, whose history indicates that Ms. Hibbard felt lightheaded, warm and nauseated "several days after having received the influenza vaccination." The doctor conducted a neurological examination, testing, among other things, her motor functions, her gait,

problems in November 2003 because, according to him, neurologic problems can begin episodically. Tr. 229.

her sensory ability, and her reflexes. The doctor stated that the “diagnosis of Guillain-Barre syndrome is unlikely” and recommended additional evaluations. She was discharged home. Exhibit 23 at 61-64.

The next day, Ms. Hibbard returned to the emergency room at Brigham & Woman’s Hospital and was admitted to the hospital. She remained in the hospital for three days. The doctors ordered various tests but, by the time of discharge, did not propose a reason for Ms. Hibbard’s problems. She continued to be diagnosed as having “malaise” and was encouraged to follow-up with Dr. Schoenbaum. Exhibit 23 at 20-21.

On January 16, 2004, Ms. Hibbard saw Brian Kim, an endocrinologist. Dr. Kim linked her current problems, which had been afflicting her since November, to the May 2003 episode of fainting. Dr. Kim did not identify hormones as the cause of her symptoms. Exhibit 23 at 254.

Over the next few months, Ms. Hibbard sought treatment with several different doctors who specialized in different areas of medicine. The list includes Dr. Jules Friedman, an otoneurologist, exhibit 10 at 15-17 & 20-22; Dr. Steven Feske, a neurologist, exhibit 23 at 272; Dr. Louise Ivers, a specialist in infectious diseases, exhibit 23 at 177-79; Dr. May Ampola, who suggested that Ms. Hibbard might have a mitochondrial disorder, exhibit 20 at 21; Dr. Rauch and Dr. Lewis, who suggested that Ms. Hibbard might have vestibular migraines, exhibit 59. Generally, these doctors did not identify what was causing Ms. Hibbard’s various problems, although the doctors did rule out some possible causes.

In April 2004, Ms. Hibbard’s primary care physician, Dr. Schoenbaum, referred her to a cardiologist, Mark Creager, for “possible dysautonomia.” He measured her blood pressure when she was sitting, which was 100/70, and stated that “[t]here was no postural decrease in blood pressure with standing for a period of up to 5 minutes.” Her heart rate was 105 in the initial part of the examination and 84 in the later part of the examination. An electrocardiogram showed sinus tachycardia. In Dr. Creager’s opinion, Ms. Hibbard did “not have any clear-cut evidence of any dysautonomic syndromes, though admittedly dysautonomia is a difficult diagnosis to make.” Dr. Creager did rule out a mitral valve prolapse. Exhibit 23 at 160-62.

On June 1, 2004, Ms. Hibbard saw Louis Caplan, a neurologist. Dr. Caplan took a history from Ms. Hibbard and examined her. Exhibit 7 at 1-2; see also tr. 382-89 (Dr. Chaudhry’s explanation for Dr. Caplan’s examination). Dr. Caplan stated that Ms. Hibbard “had a postinfectious neuropathy with autonomic features. This

would be kind of a Guillain Barre with partial dysautonomia.” Dr. Caplan referred her to an expert in Guillain-Barré syndrome, Dr. Gorson. Exhibit 7 at 1-2.

Dr. Morgan credited Dr. Caplan as being the first doctor to “put together” what was happening to Ms. Hibbard. Tr. 25-26. Dr. Chaudhry stated that Ms. Hibbard was continuing to worsen until her symptoms became definable by Dr. Caplan. Tr. 226-27. Dr. Chaudhry disagreed with Dr. Caplan’s conclusion that Ms. Hibbard had Guillain-Barré syndrome. Tr. 308.

The doctor to whom Dr. Caplan referred Ms. Hibbard was Dr. Gorson. His assessment is valuable because Dr. Gorson is an expert on Guillain-Barré syndrome. Tr. 82; tr. 139. Dr. Gorson stated that her detailed neurological examination was normal. “Routine nerve conduction studies were pristine.” Dr. Gorson also conducted at least one test for her autonomic nervous system, the heart rate variability test, and the results were borderline. Dr. Gorson stated that “I can tell you that she does not have electrophysiologic features, nor clinical features, of typical Guillain-Barre syndrome.” He also said that “It is certainly possible that she developed a modest dysautonomic neuropathy following a nonspecific viral illness or even the flu vaccination back in November.” Dr. Gorson suggested that Ms. Hibbard may have POTS and recommended several different tests “to confirm an autonomic element to her disorder.” Exhibit 3 at 2-3.

Ms. Hibbard underwent a series of tests on her autonomic nervous system on June 16, 2004. The tests were conducted by Dr. Christopher Gibbons, who was supervised by Dr. Roy Freeman. Exhibit 7 at 4. Dr. Freeman is considered to be the country’s (and possibly the world’s) leading expert in autonomic dysfunction. Tr. 231. One of the tests, the tilt table test, showed that Ms. Hibbard had “exaggerated postural tachycardia.” Other tests of the parasympathetic and sympathetic functions were in the normal range. Dr. Gibbons’s report stated that “[a]n exaggerated postural tachycardia has been associated with a mild or early autonomic neuropathy.” Exhibit 7 at 3-4; see also tr. 370-74 (Dr. Chaudhry’s discussion of Dr. Gibbons’s testing); tr. 549-50 (Dr. Morgan’s discussion of Dr. Gibbons’s testing). Dr. Freeman later noted that “it is unclear . . . to the extent to which autonomic dysfunction is contributing to her symptoms.” Exhibit 7 at 9.

After Ms. Hibbard’s treatment with Dr. Freeman, she was seen on a periodic basis by Dr. Novak. On September 1, 2004, Dr. Novak obtained a history of Ms. Hibbard’s present illness and recorded that Dr. Freeman’s autonomic testing showed “POTS and orthostatic hypotension and mild autonomic neuropathy.” Dr. Novak assessed her as having “autonomic neuropathy” and requested additional testing. Dr.

Novak also stated that the “[r]elationship to flu shots remain, however, unclear.” Exhibit 19 at 3-4. Dr. Novak or his associates continued to see Ms. Hibbard for various complaints through 2007. *Id.*, *passim*. On February 16, 2010, which was shortly before the second day of the hearing, Ms. Hibbard saw Dr. Novak again. In the report from this visit, Dr. Novak’s impression was “[d]ysautonomia.” Exhibit 58 at 1.

III. Standards for Adjudication

Petitioners are required to prove their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master’s decision that petitioners were not entitled to compensation); see also *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357 (2000); *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty). In this regard, “close calls regarding causation are resolved in favor of injured claimants.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

IV. Analysis

The preliminary question to be resolved is whether Ms. Hibbard suffers from autonomic neuropathy.⁹ When there is some dispute about a petitioner’s diagnosis,

⁹ The following analysis uses the term “autonomic neuropathy” to mean damage to nerves in the autonomic nervous system. In this context, “autonomic neuropathy” is not synonymous with “dysautonomia.”

special masters may find whether a preponderance of evidence supports any proposed diagnosis before evaluating whether a vaccine caused that illness. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345-46 (Fed. Cir. 2010). Here, the need to determine whether the nerves in Ms. Hibbard's autonomic nervous system are damaged is particularly acute because Dr. Morgan's theory of how the flu vaccine caused an injury to Ms. Hibbard is based upon an assertion that Ms. Hibbard's nerves are damaged. See exhibit 36 at 5 (Dr. Morgan's September 17, 2008 report, stating "Ms. Hibbard sustained . . . [an] autonomic neuropathy"); exhibit 38 at 2 (Dr. Morgan's February 17, 2009 report, stating Ms. Hibbard's postural orthostatic tachycardia "is a finding in conjunction with other findings from her postvaccinal autonomic neuropathy.").¹⁰

A. Does Ms. Hibbard Have Autonomic Neuropathy?

A preponderance of the evidence supports a finding that Ms. Hibbard does not have autonomic neuropathy. The reason for this finding is that when Ms. Hibbard was tested for signs of autonomic neuropathy, the results were normal.

There actually is little dispute about the meaning of these tests. In the first hearing, Dr. Chaudhry asserted that Ms. Hibbard did not have autonomic neuropathy because tests were normal. Tr. 210-16. Dr. Chaudhry explained that Ms. Hibbard's condition "is unlikely to be even an autonomic neuropathy." Tr. 261. Following this testimony, respondent was ordered to cite the exhibit number and page number of the tests on which Dr. Chaudhry relied. Order, filed Aug. 13, 2009. The Secretary filed this report from Dr. Chaudhry as exhibit H on September 25, 2009, approximately four months before the hearing resumed.

Exhibit H contains a thorough list of various tests of Ms. Hibbard's autonomic nervous system, including postural hypotension, Valsalva maneuver, and epinephrine levels. The tests, except for a few "borderline" results, were all normal. See exhibit H and citations therein.

Additional details about exhibit H are not really needed because Dr. Morgan agreed that Ms. Hibbard did not have any objective signs for a neuropathy. Tr. 517; see also tr. 155-56. This acknowledgment prompts the question, if there are no signs that Ms. Hibbard has autonomic neuropathy, why does Dr. Morgan assert that she has one?

¹⁰ Ms. Hibbard has advanced only a theory that the flu vaccine can cause POTS by damaging the autonomic nerves. Whether the flu vaccine can cause POTS some other way was not presented by Dr. Morgan.

Dr. Morgan opined that Ms. Hibbard has autonomic neuropathy because she suffers from POTS. Tr. 520; tr. 37-38; tr. 559-61. Ms. Hibbard similarly argues that “A finding of POTS indicates damage to the sympathetic nervous system.” Pet’r Reply at 4 n.6.

This argument is not persuasive. Although there is no dispute that Ms. Hibbard suffers from POTS, tr. 221; tr. 252-53, POTS does not always mean that the nerves in the autonomic nervous system are damaged. For example, the Mayo Clinic article on which Dr. Morgan relied reported that half the POTS patients had peripheral neuropathy. Exhibit 38, tab A (Thieben) at 312. The other half did not. Tr. 262; tr. 275-76. Thus, POTS has more than one cause. See tr. 532 (Dr. Morgan’s testimony that not all cases of POTS have a peripheral neuropathy); exhibit 38 at 2 (Dr. Morgan’s February 17, 2009 report, stating “postural tachycardia can be seen in many conditions.”).

Ms. Hibbard did not have other problems that people who have POTS associated with an autonomic neuropathy have. For example, Ms. Hibbard did not have low blood pressure when standing, heart rate variation with deep breathing, sweating abnormalities, or an abnormal skin sympathetic test. Tr. 432; see also exhibit H (listing tests). Her normal responses to these tests mean that her autonomic nervous system functioned.¹¹

Admittedly, some treating doctors indicated that Ms. Hibbard had autonomic neuropathy. A prominent example is Dr. Caplan (exhibit 7 at 1-2). Another is Dr. Novak. Exhibit 19, *passim*.¹²

These reports of autonomic neuropathy, however, must be weighed in the context of records from other doctors. 42 U.S.C. § 300aa—13(a) (instructing special masters to consider the record as a whole); Snyder v. Sec’y of Health & Human Servs., 88 Fed. Cl. 706, 745 n.67 (2009). Other doctors seemed to refrain from

¹¹ Dr. Morgan provided a list of signs and symptoms pertaining to Ms. Hibbard. Dr. Morgan associated most of these symptoms with “dysautonomia,” not autonomic neuropathy. Exhibit 52. Further, Dr. Chaudhry explained that this list of symptoms on exhibit 52 did not support a diagnosis of autonomic neuropathy. Tr. 366-70.

¹² Dr. Novak’s most recent report used the term “dysautonomia,” rather than “autonomic neuropathy.” Exhibit 58.

concluding that Ms. Hibbard had autonomic neuropathy. For example, Dr. Gorson, the expert in Guillain-Barré syndrome, said that autonomic neuropathy was a “possibility.” When Dr. Gorson stated that autonomic neuropathy was a possibility (June 7, 2004), Ms. Hibbard had been the subject of few tests for autonomic neuropathy. One test, the heart rate variability test, produced a “borderline” result. On the other hand, Ms. Hibbard “appeared to have normal vasomotor function and sweating upon inspection.” With that background, Dr. Gorson was “hesitant to confirm autonomic neuropathy to her disorder without more objective data to support such entity.” Exhibit 3 at 2-3.

Additional autonomic testing was performed under the auspices of Dr. Freeman on June 16, 2004. The heart rate variability test was normal, the Valsalva maneuver was normal, and the sympathetic skin response was present. However, Ms. Hibbard demonstrated exaggerated postural tachycardia on standing. According to Dr. Gibbons this was a “non-specific finding.” Exhibit 7 at 3; see also tr. 390-92 (Dr. Chaudry explaining Dr. Gibbons’s report). The expert in the autonomic nervous system, Dr. Freeman, stated, after reviewing various test results, “it is unclear . . . to the extent to which autonomic dysfunction is contributing to her symptoms.” Exhibit 7 at 9.

In short, the evidence weighs in favor of a finding that Ms. Hibbard did not have autonomic neuropathy. Two of the world’s leading doctors, Dr. Gorson and Dr. Freeman, did not find that Ms. Hibbard had autonomic neuropathy. Dr. Chaudhry also opined that Ms. Hibbard did not have autonomic neuropathy. Dr. Chaudhry’s reason for his opinion – that the tests of Ms. Hibbard’s autonomic nervous system returned normal results – is persuasive. Conversely, the basis for Dr. Morgan’s opinion – that Ms. Hibbard suffers from POTS – is not persuasive because it fails to account for the substantial number of people who have POTS without autonomic neuropathy.

B. Has Ms. Hibbard Met the *Althen* Test?

After determining that Ms. Hibbard does not suffer from the condition asserted by her expert, the next step is evaluating whether Ms. Hibbard satisfies the test for finding entitlement for non-Table cases. This test is set forth in Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

An extensive analysis of the Althen elements is not needed. Once it is determined that Ms. Hibbard does not suffer from autonomic neuropathy as opined by Dr. Morgan, the remainder of her case ceases to be logical. See Doe 60 v. Sec’y of

Health & Human Servs., 94 Fed. Cl. 597, 611-12 & 623-34 (2010) (affirming special master's decision to determine whether the petitioner suffered from any conditions for which she sought compensation before conducting the Althen analysis), appeal docketed No. 2011-5004 (Fed. Cir. Oct. 4, 2010).

Through Dr. Morgan, Ms. Hibbard advances the theory that the flu vaccine can lead to an immune-mediated attack on nerves. Ms. Hibbard claims that either the myelinated or unmyelinated nerves in the sympathetic component of the autonomic nervous system were attacked. Ms. Hibbard argues that she suffered a variant of Guillain-Barré syndrome. Tr. 50-51; tr. 75-80; Pet'r Br. at 32-37.

Ms. Hibbard's theory that the flu vaccine can cause all the problems suggested by Dr. Morgan was poorly supported.¹³ However, these concerns can be set aside because even assuming that Ms. Hibbard has proposed a reliable theory of what can happen, Ms. Hibbard has not presented preponderant evidence that this happened to her. Dr. Morgan's theory causally connecting the flu vaccine to Ms. Hibbard's problem pertains to the sympathetic component of her autonomic nervous system. But, the nerves in Ms. Hibbard's autonomic nervous system were not damaged. The absence of preponderant proof on this point makes Dr. Morgan's opinion illogical, and, thus, Ms. Hibbard cannot satisfy the Althen test.

¹³ For example, Ms. Hibbard did not persuasively explain why an attack would be limited to nerves in the sympathetic component of her autonomic nervous system. These nerves are adjacent to nerves of the parasympathetic component and nerves of the somatic nervous system, which transmit motor and sensory function. See tr. 227-28; Pet'r Trial Exhibit at 6. Ms. Hibbard makes no claim that these nerves were damaged.

Additionally, Ms. Hibbard's claim that she suffered from a variant of Guillain-Barré syndrome seems far-fetched. Ms. Hibbard was examined by Dr. Gorson, a leading expert in the country on Guillain-Barré syndrome. Dr. Gorson stated that she did not have this condition. Exhibit 3 at 3.

V. Conclusion

On November 1, 2003, Ms. Hibbard received a flu vaccination. In late November 2003, Ms. Hibbard's health declined. She was eventually diagnosed as having POTS, a form of dysautonomia. Although her autonomic nervous system was not functioning properly, the reason for the dysfunction is not with the nerves in the autonomic nervous system. Tests consistently showed that the autonomic nerves were normal.

Ms. Hibbard claimed that the flu vaccination caused her subsequent health problems and based her claim upon the opinion of Dr. Morgan. A preponderance of evidence contradicts Dr. Morgan's assessment that Ms. Hibbard suffered autonomic neuropathy. Without persuasive evidence of autonomic neuropathy, Ms. Hibbard did not meet her burden of proof.

Ms. Hibbard is not entitled to compensation. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERED.

s/ Christian J. Moran
Christian J. Moran
Special Master